DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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New Animal Drugs for Use in Animal Feeds; Decoquinate, Monensin, and Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved, single-ingredient decoquinate, monensin, and tylosin Type A medicated articles to make three-way combination drug Type B and Type C medicated feeds used for prevention of coccidiosis, improved feed efficiency, and reduction of incidence of liver abscesses in growing-finishing cattle fed in confinement for slaughter.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–149 that provides for use of DECCOX® (27.2 gram per pound (g/lb) decoquinate), Rumensin® (20, 30, 45, 60, 80, or 90.7 g/lb monensin activity as monensin sodium) and TYLAN® (10, 40, or 100 g/lb tylosin phosphate) Type A medicated articles to make three-way combination Type B and Type C medicated feeds for use in growing-finishing cattle fed in confinement for slaughter. The Type C medicated feeds contain 13.6 to 27.2 g/ton decoquinate, 5 to 30 g/ton monensin, and 8 to 10 g/ton tylosin, and are used for the prevention

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of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, improved feed efficiency, and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces pyogenes*. The NADA is approved as of November 16, 2000, and the regulations in 21 CFR 558.195 and 558.625 are being amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.195 is amended in the table in paragraph (d) by adding an entry after ''Monensin 5 to 30'' and before ''Chlortetracycline approximately 400'' to read as follows:

§ 558.195 Decoquinate.

* * * * *

(d) * * *

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
	Monensin 5 to 30; plus tylosin 8 to 10	Cattle fed in confinement for slaughter; for prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*, improved feed efficiency, and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces pyogenes*.	Feed only to cattle fed in confinement for slaughter. Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb body weight per day, 50 to 360 mg of monensin per head per day, and 60 to 90 mg of tylosin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Also see (c)(1) of this paragraph and § 558.355(d)(8). Monensin as monensin sodium and tylosin as tylosin phosphate provided by 000986 in § 510.600(c) of this chapter.	046573
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§ 558.355 [Amended]

3. Section 558.355 *Monensin* is amended in paragraph (f)(7) by adding ''alone or with tylosin'' after ''decoquinate''.

4. Section 558.625 is amended by redesignating paragraphs (f)(2)(i) through (f)(2)(v) as (f)(2)(ii) through (f)(2)(vi), and by adding paragraph (f)(2)(i) to read as follows:

§ 558.625 Tylosin.

* * * * *

(f) * * *

(2) * * *

(i) Decoquinate and monensin as in § 558.195.

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Dated: 12/26/00
December 26, 2000

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

SF Sundlof

Stephen F. Sundlof
Director
Center for Veterinary Medicine

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